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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,984	04/02/2001	Sharat Singh	0225-0033.25	2489

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 03/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/824,984

Applicant(s)

Singh et al.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 20) ☐ Other: _____

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 09/824,247. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-4 of instant application claims a method for detecting binding or interaction between each or any of a plurality of ligands and one or more target antigens in which the same eTag probe used as in the method of copending application in which claims 1-10

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of copending Application No. 09/825,247 is for detecting each or any of a plurality of known, selected nucleotide target sequence. Thus, an ordinary skill in the art would have been motivated to apply the method of copending application to detect binding or interaction between each or any of a plurality of ligands and one or more target antiligands because the eTag probe has the same feature as the eTag probe used in copending application and the ligands and antiligands in instant application encompass a nucleic acid sequence which will have corresponding complementary sequence to be hybridized.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being respectively unpatentable over claims 1-19 of copending Application No. 09/825,245, claims 1-15 of copending Application No. 09/825, 246, claims 1-10 of copending Application No 09/824,905, claims 1-4 of copending Application No. 09/824,861, claims 1-4 of copending Application No. 09/824,851 and claims 1-20 of copending Application No. 09/825,244. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of instant application uses the eTag probe which has the same features of the eTag probe claimed in the copending applications as listed above. Thus, an ordinary skill in the art would have been motivated to used the eTag probe in instant method because it was well known in the art at the time of instant invention to use a probe for detection.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1- 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a Claim 4 is vague and indefinite because it is unclear what is the definition of the language "a particle" and "mass group" in the specification since every molecule has mass group. Clarification is required.

b. Claims 1-4 are vague and indefinite because of the language "the contacted antiligand(s)". The language has no antecedent basis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Grossman et al. (5,470,705)

Grossman et al. disclose a method of detecting the binding of interaction between each or any of a plurality of ligands and one or more target antiligands comprising:

(a) reacting the antiligand(s) with a set of electrophoretic tag (e-tag) probes as claimed in claim 1(a);

(b) treating the contacted antiligand(s) with the cleaving agent, thereby to produce a mixture of e-tag reporters having the form $(D, M_j) - L'$, and uncleaved and/or partially cleaved probes.

(c) exposing said mixture to a capture agent effective to bind to uncleaved or partially cleaved probes;

(d) fractionating e-tag reporters having the form $(D, M_j) - L'$ by electrophoresis, to effect separation of the e-tag reporters, and

(e) identifying the electrophoretic mobilities of one or more electrophoretic bands, each band uniquely corresponding to an e-tag reporter that is uniquely assigned to a target antiligand (See the Abstract, column 2, lines 65-67 to column 3, lines 1-10 and lines 55-64, column 19, lines 62-67, column 20, lines 1-25).

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None of the reference discloses that the contacted antiligand is treated with nuclease and then the uncleaved probe is immobilized, but not the reporter probe. However, the claim language does not specify the order of the steps in the method.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,470,705) as applied to claims 1 and 4 above, and further in view of Babon et al. (5,851,770).

The teachings of Grossman et al. are set forth in section 7 above.

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Grossman et al. do not disclose capture agent which is avidin or streptavidin or antigen/antibody.

Babon et al. disclose a method for detecting one or more mismatches between a first and second nucleic acid in which the heteroduplex formed between the first and second nucleic acid sequence is biotinylated and captured by binding to streptavidin-magnetic beads (See column 7, lines 53-66) and the captured heteroduplex are then cleaved, the cleaved fragment is analyzed by gel electrophoresis (See column 8, lines 1-4). The capture ligand and capture agent includes antigen/antibody or DNA binding protein and its DNA binding site (See column 18, lines 13-24).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Grossman et al. by using the capture ligand/agent attached to the oligonucleotide probe as taught by Babon et al. because the substitution of one known reagent with known properties for a second well known reagent with known properties would have been prima facie obvious to an ordinary skill in the art at the time of instant invention with a reasonable expectation of success in the absence of an unexpected results.

10. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.


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Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

March 12, 2002


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600